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**From:** Jedzinak, Daniel [Daniel.Jedzinak@fda.hhs.gov]  
**Sent:** 7/27/2017 1:58:21 PM  
**To:** McNally, Robert [Mcnally.Robert@epa.gov]  
**CC:** Kux, Leslie [Leslie.Kux@fda.hhs.gov]; Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]  
**Subject:** RE: GFI 236  
**Attachments:** GFI\_236 - Regulation of Mosquito-Related Products - Final 5-26-17\_EOP a....doc; 2017-64 NOA for Mosquitoes Jurisdiction Guidance - 6-21-17 clean.docx; FDA memo for OMB on Mosquitoes jurisdiction guidance 7-26-17 clean.docx

Bob et al.,

So that folks on the EPA side are on the same page with FDA, I'm attaching:

1. The mosquitoes GFI 236, with the margin comments we got from OMB on 7/25
2. The notice of availability, which we had also provided to OMB reviewers weeks ago
3. The background memo, which we provided yesterday at OMB's request

For the 3 pm call this afternoon, OMB has requested:

- a general walk-through of the policy and clarification on why it is desirable to do it this way
- discuss FDA's statutory analysis and whether it makes sense to spell it out any further in the document (so it would be helpful to have some GC folks on the line)

The catalyst for the call and backgrounder, is that OMB told us that some of their reviewers weren't around for the draft guidance and have been a little confused by the discussion in the final guidance.

Thanks,

Dan

FDA Office of Policy/RPMS  
240 762 2309

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**From:** Nalubola, Ritu  
**Sent:** Thursday, July 27, 2017 9:54 AM  
**To:** McNally, Robert  
**Cc:** Kux, Leslie; Jedzinak, Daniel; Keigwin, Richard; Hartman, Mark  
**Subject:** RE: GFI 236

Bob – Quick note to flag OMB call today at 3 pm. You should've received Outlook notice from Dan. Hope you or others from EPA will be able to join (to clarify/discuss EPA comment, as needed).

Thanks much!

Ritu

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**From:** McNally, Robert [mailto:Mcnally.Robert@epa.gov]  
**Sent:** Tuesday, July 25, 2017 3:34 PM  
**To:** Nalubola, Ritu  
**Cc:** Kux, Leslie; Jedzinak, Daniel; Keigwin, Richard; Hartman, Mark  
**Subject:** RE: GFI 236

Yes, we would like to be part of the call. thanks

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**From:** Nalubola, Ritu [<mailto:Ritu.Nalubola@fda.hhs.gov>]  
**Sent:** Tuesday, July 25, 2017 2:58 PM  
**To:** McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>  
**Cc:** Kux, Leslie <[Leslie.Kux@fda.hhs.gov](mailto:Leslie.Kux@fda.hhs.gov)>; Jedzinak, Daniel <[Daniel.Jedzinak@fda.hhs.gov](mailto:Daniel.Jedzinak@fda.hhs.gov)>  
**Subject:** GFI 236

Hi Bob – Thanks for the conversation just now. Also appreciate your clarification on EPA comment about scope of 236/broader insects issue.

So, I'm hearing that the interagency call to go over interagency comments on the document will likely be Thursday 3 pm or mid-next week. It would be helpful if you could join that call when it is scheduled – I expect you all will see information about that call from OIRA. Looping in Dan Jezinak on our side who is coordinating that process, in case you have any questions.

Thanks,  
Ritu

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